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# Implementing Rapid HIV Testing in the United States

## Overview and Background

Bernard M. Branson, M.D.  
Centers for Disease Control and Prevention

The Role of  
Aids Virus Antibody  
Testing  
IN THE PREVENTION  
AND  
CONTROL OF AIDS

*February 24-25, 1987  
Atlanta, Georgia*

U.S. Department of Health and Human Services  
Public Health Service  
Centers for Disease Control

# Questions: 1987

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- Should...
  - persons attending STD clinics have a test for HIV antibody?
  - persons attending drug treatment programs have a test for HIV antibody?
  - the sexual partners of people with HIV infection be notified about their potential exposure and tested and counseled?

# Questions: 1987

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## ■ Should...

- persons attending family planning services have a test for HIV antibody?
- pregnant women have a test for HIV antibody as early in pregnancy as possible?
- HIV antibody testing be a routine part of a premarital testing program?
- Every patient admitted to a hospital be tested for HIV antibody?

# Questions: 1987

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- How...

- Can HIV antibody test results be used for appropriate medical and public health purposes without their being used for discrimination or social ostracism?

July 27, 1989 / Vol. 28 / No. 30

# MORBIDITY AND MORTALITY WEEKLY REPORT

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## Recommendations and Reports

### Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections

U.S. Department of Health and Human Services  
Public Health Service  
Centers for Disease Control  
Center for Infectious Diseases  
AIDS Program  
Atlanta, Georgia 30333

# 1989 Recommendation

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- No positive test results should be given to clients/patients until a screening test has been repeatedly reactive (i.e., two or more tests) on the same specimen, and a supplemental, more specific test such as the Western blot has been used to validate those results.



January 15, 1993 / Vol. 42 / No. RR-2

**MMWR**

*Recommendations  
and  
Reports*

**MORBIDITY AND MORTALITY WEEKLY REPORT**

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**Recommendations for HIV Testing  
Services for Inpatients and  
Outpatients in Acute-Care Hospital  
Settings**

**and**

**Technical Guidance  
on HIV Counseling**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Centers for Disease Control  
and Prevention (CDC)  
Atlanta, Georgia 30333



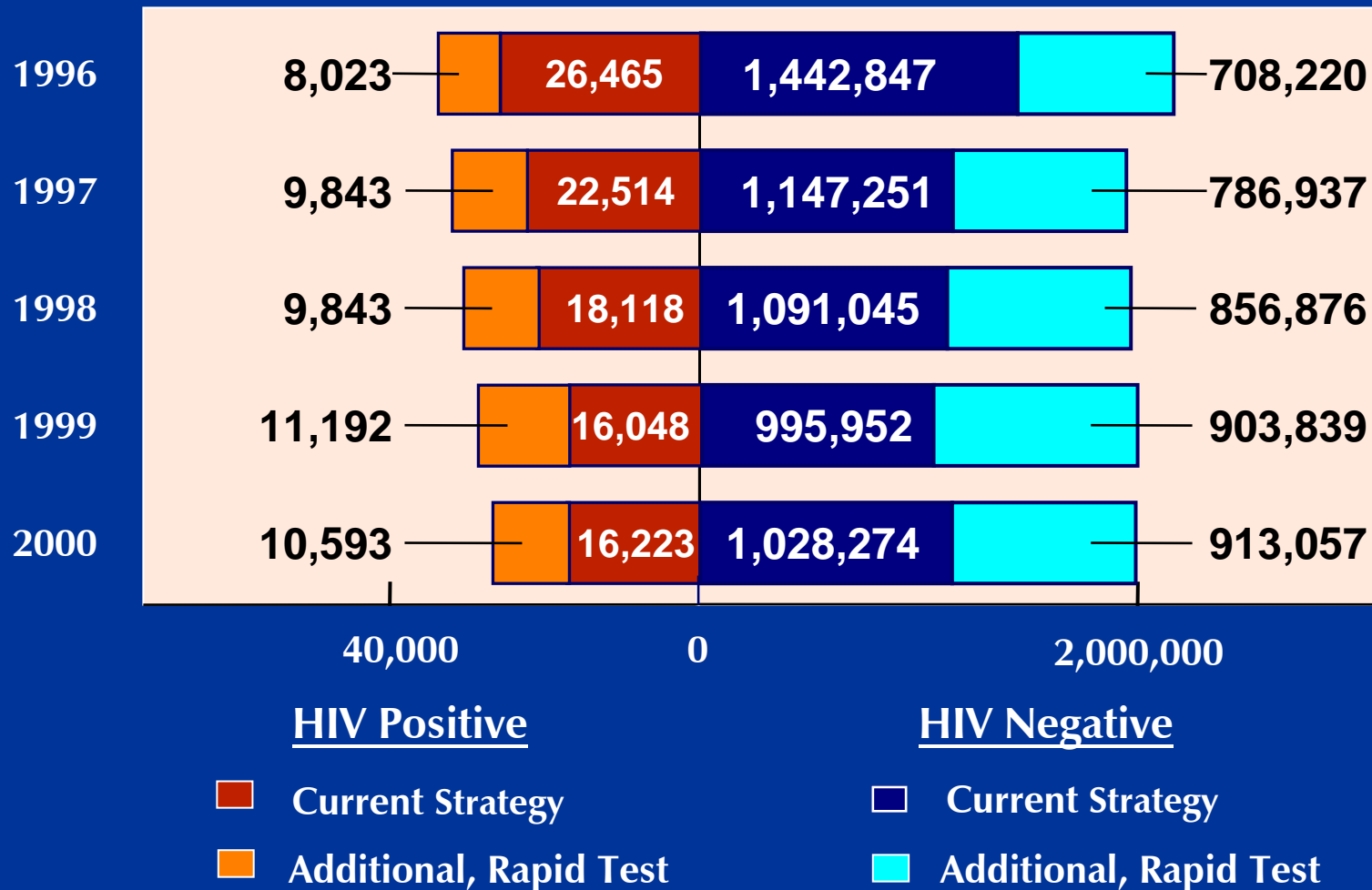


# Proportion of persons who do not return for their HIV test results

	<u>HIV Positive</u>	<u>HIV Negative</u>
1995	25%	33%
1996	26%	33%
1997	33%	42%
1998	38%	44%
1999	43%	48%
2000	42%	47%

*Source: CDC Client Record Database, Publicly-funded HIV testing*

# What if rapid HIV tests were used in all public testing sites?



# MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

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## Update: HIV Counseling and Testing Using Rapid Tests — United States, 1995

Approximately 25 million persons each year in the United States are tested for antibody to human immunodeficiency virus (HIV). Publicly funded counseling and testing (CT) programs conduct approximately 2.5 million of these tests each year. CT can have important prevention benefits (1); however, in 1995, 25% of persons testing HIV-positive and 33% of persons testing HIV-negative at publicly funded clinics did not return for their test results (2). Rapid tests to detect HIV antibody can be performed in an average of 10 minutes (3), enabling health-care providers to supply definitive negative and preliminary positive results to patients at the time of testing, potentially increasing the overall effectiveness of CT. In comparison, results from enzyme immunoassays (EIAs) currently used for HIV screening often are not available for 1–2 weeks. To quantify the potential advantages and disadvantages of using rapid tests for CT, CDC estimated the potential impact on the number of persons who would learn their HIV-test results. This report summarizes the results of the analysis and provides the basis for changing the Public Health Service (PHS) recommendations for providing HIV-test results.\*

A decision model was designed to compare the current HIV-CT procedure and a strategy using the commercially available rapid test (Single Use Diagnostic System [SUDS] HIV-1 Test, Murex Corporation, Norcross, Georgia<sup>†</sup>). The analysis was based on the number of tests performed and the HIV prevalence reported from publicly funded testing sites in the 1995 client record CT database (CDC, unpublished data, 1996). The number of persons who would learn their true HIV status under each strategy and the number who would receive a preliminary false-positive rapid-test result were calculated using the HIV prevalence at different types of testing sites, the percentage of those who received results at each site type (Table 1), and the published sensitivity and specificity of the EIA and the rapid test. The client record database was used to determine the proportion of persons who received their HIV test results under the current strategy. Data from clinical trials were used for the percentage of persons

\*Single copies of this report will be available until March 27, 1999, from CDC's National AIDS Clearinghouse, P.O. Box 6003, Rockville, MD 20849-6003; telephone (800) 458-5231 or (301) 519-0459.

<sup>†</sup>Use of trade names is for identification only and does not imply endorsement by CDC or the U.S. Department of Health and Human Services.

# 1998 Recommendation

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- Health care workers should provide preliminary positive rapid test results before confirmatory results are available in situations where tested persons benefit.

# Interpreting Screening Test Results

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*For a laboratory test:*

***Sensitivity:*** Probability test=positive if patient=positive

***Specificity:*** Probability test=negative if patient=negative

***Predictive value:***

Probability patient=positive if test=positive

Probability patient=negative if test=negative

**Example:** Test 1,000 persons  
Test Specificity = 99.6% (4/1000)

HIV prevalence = 10%

True positive: 100      False positive: 4

Positive predictive value:  $100/104 = 96\%$

**Example:** Test 1,000 persons

Test Specificity = 99.6% (4/1000)

HIV prevalence = 10%

True positive: 100

False positive: 4

Positive predictive value:  $100/104 = 96\%$

HIV prevalence = 0.4%

True positive: 4

False positive: 4

Positive predictive value:  $4/8 = 50\%$

# Predictive Value: Single Screening Test

**Test Specificity 99.8%**

<u>HIV Prevalence</u>	<u>True +</u>	<u>False +</u>	<u>Predictive Value Positive</u>
10%	100	2	98%
5%	50	2	96%
2%	20	2	91%
1%	10	2	83%
0.5%	5	2	71%
0.2%	2	2	50%
0.1%	1	2	33%

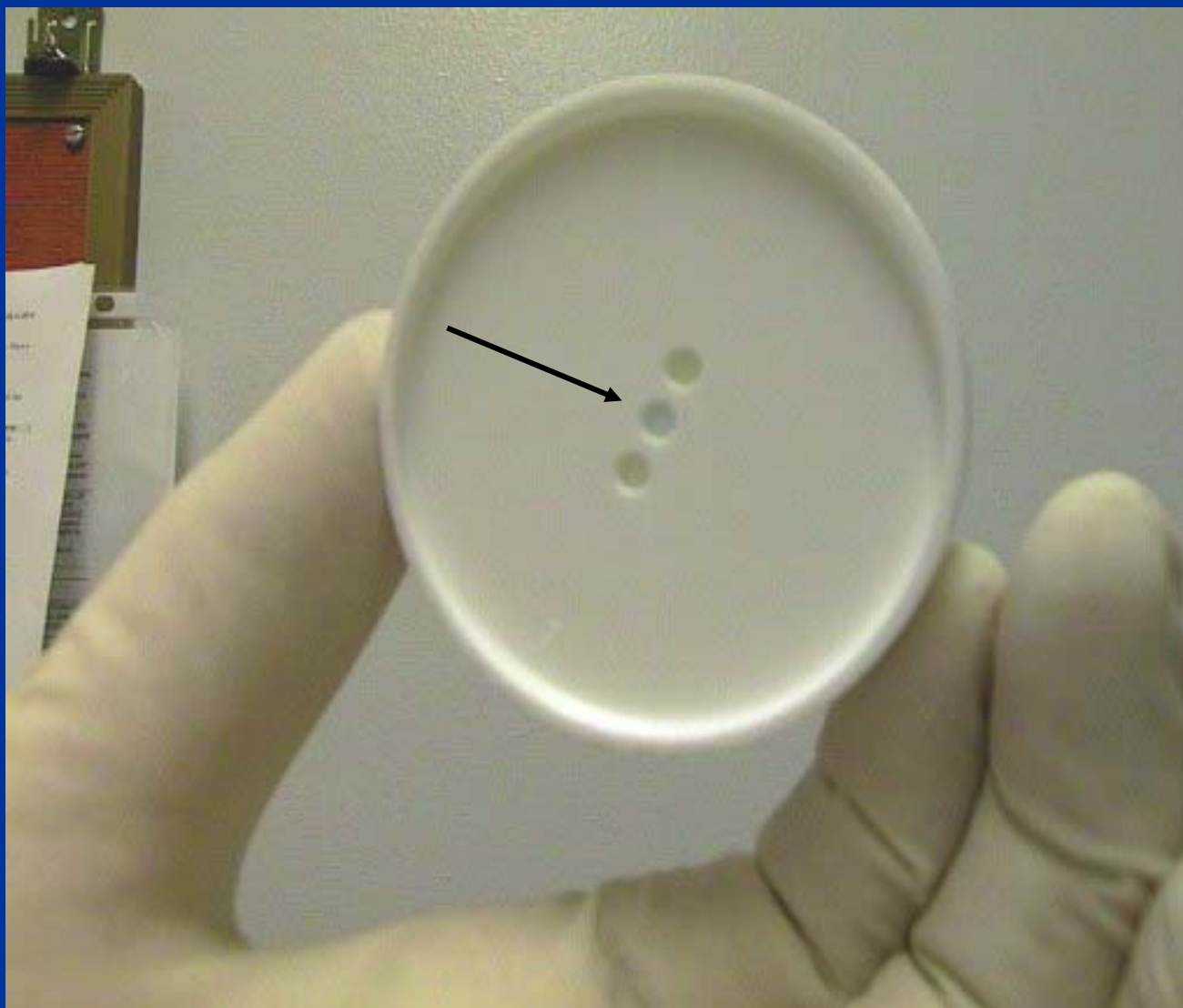




**Centrifuge to obtain serum or plasma**



**Several reagent steps**



**Blue color with reactive HIV test**



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**MORBIDITY AND MORTALITY**  
**WEEKLY REPORT**

*Recommendations  
and  
Reports*

**Revised Guidelines for HIV Counseling,  
Testing, and Referral**

**and**

**Revised Recommendations  
for HIV Screening  
of Pregnant Women**

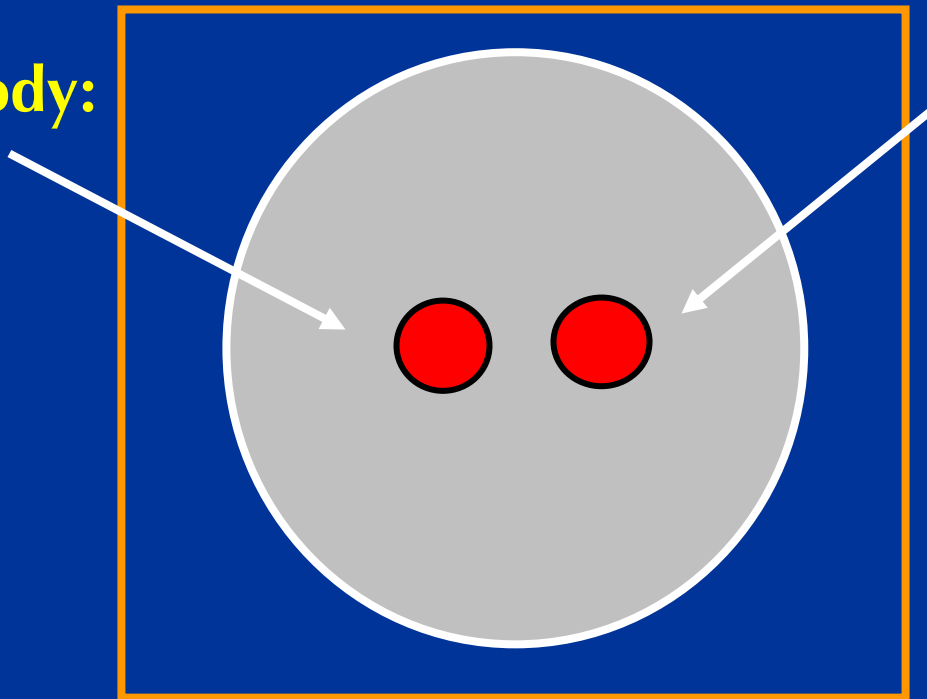
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention (CDC)  
Atlanta, GA 30333



# Principle: Flow-through devices

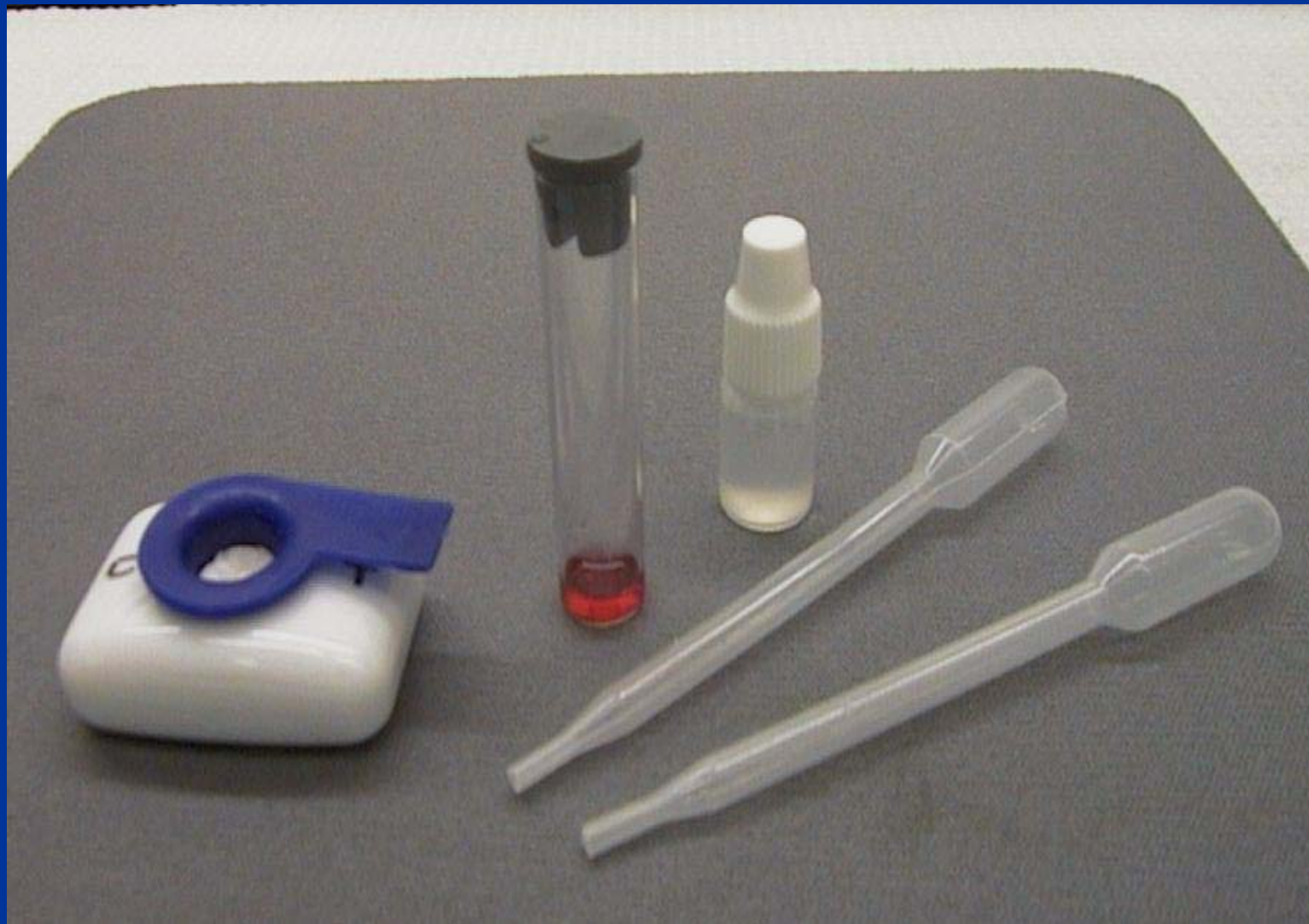
Microparticles immobilized in membrane  
form test spots

Control antibody:  
-Anti-IgG  
-Anti-gold



HIV-1 peptide





## MedMira HIV 1-2



**Reconstitute Conjugate with buffer**



**Add 1 drop buffer to cartridge**

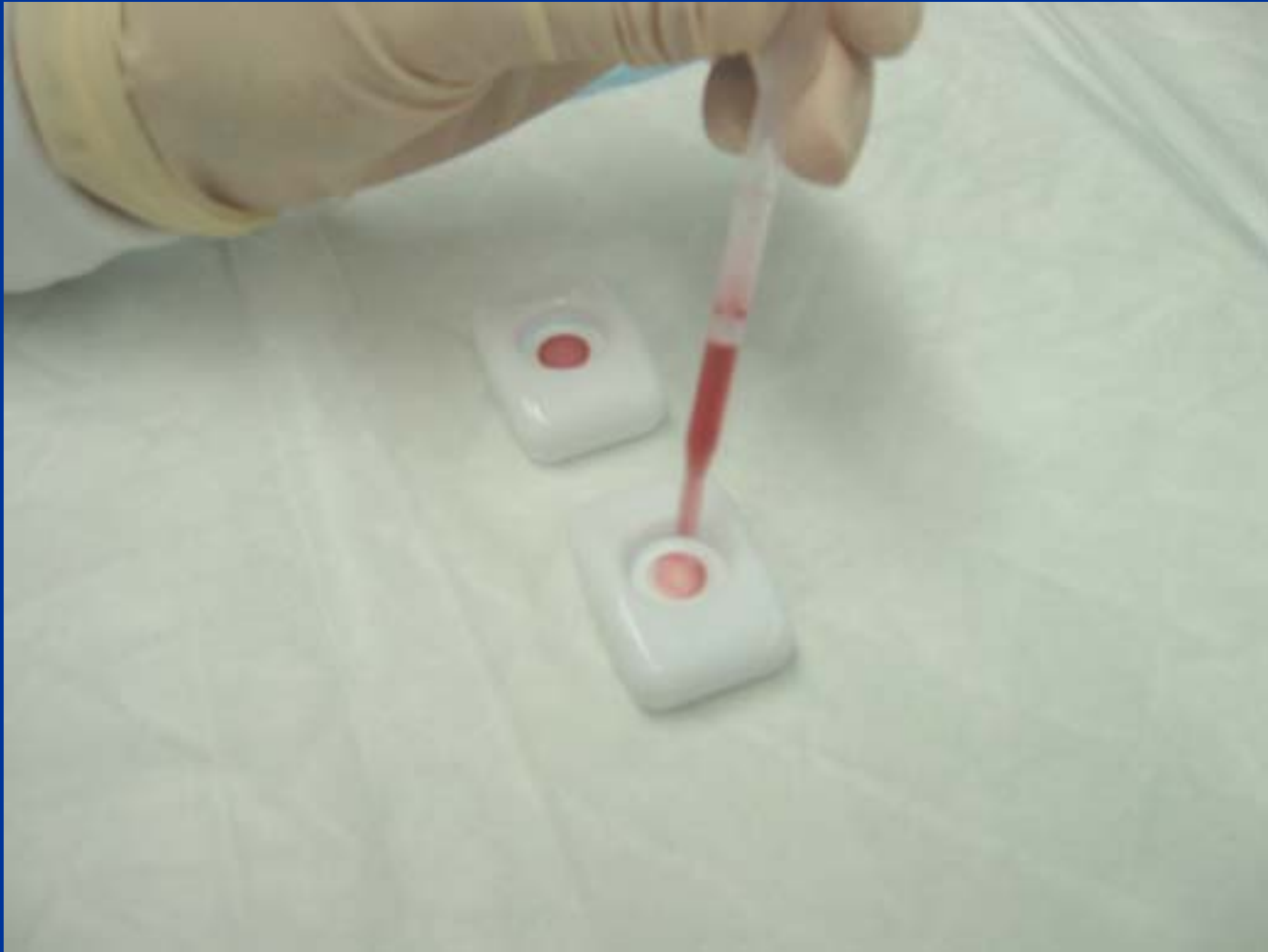




**Add 1 drop serum to cartridge**



**Wash with buffer**



**Add conjugate to cartridge; wash**



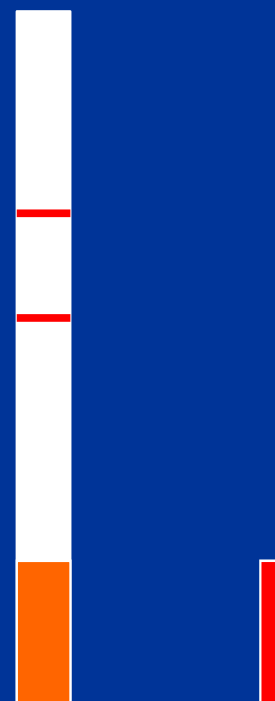
**Read results immediately**

# Immunochromatography

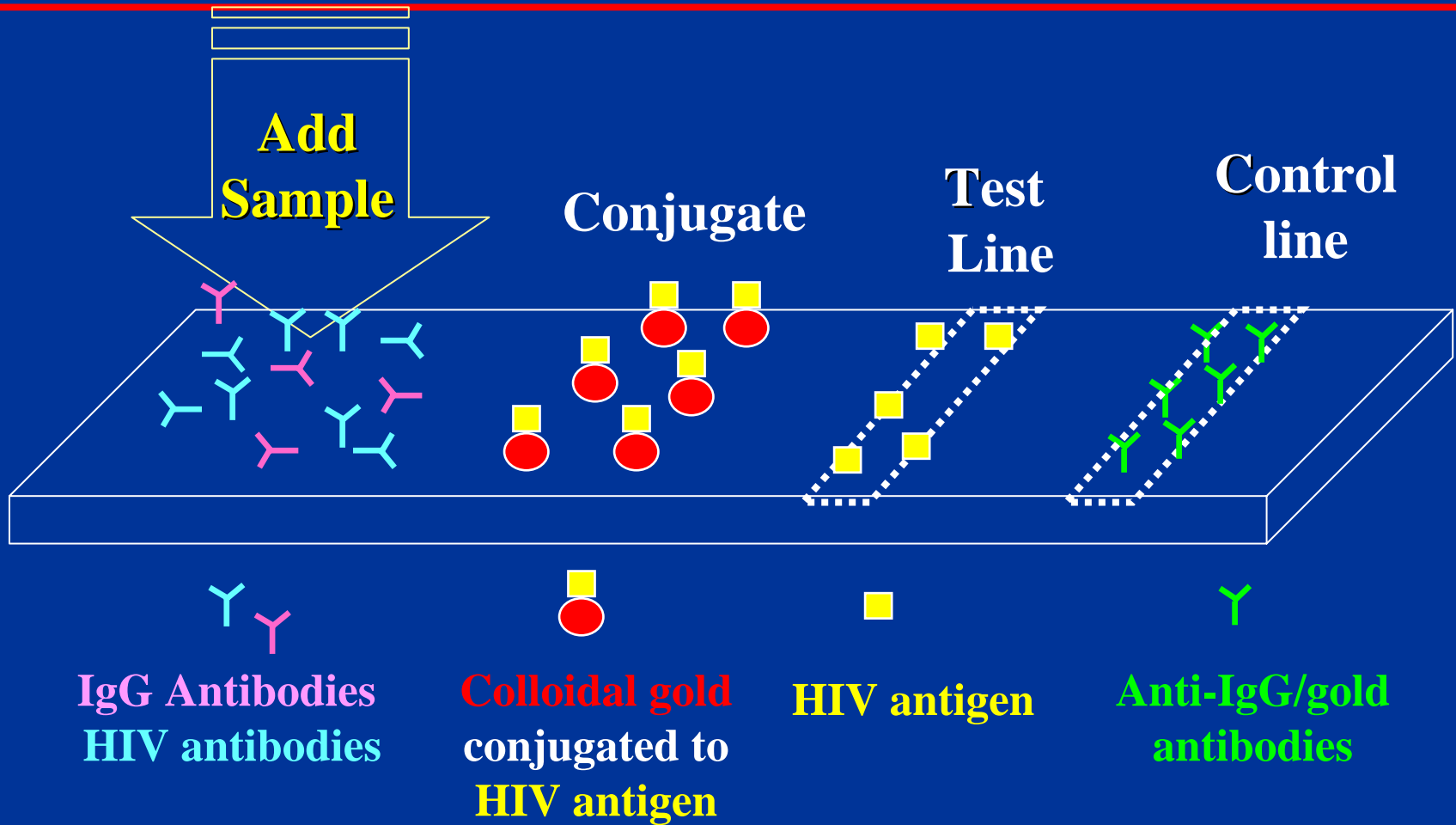
## ■ Lateral Flow Devices

- Determine
- Doublecheck
- HemaStrip
- OraQuick
- Unigold

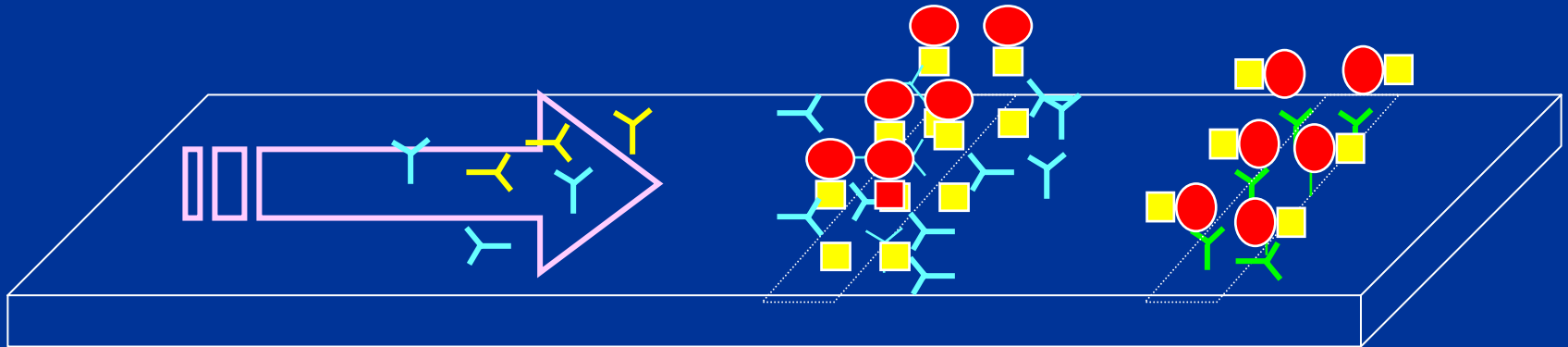
Control  
HIV Antigen



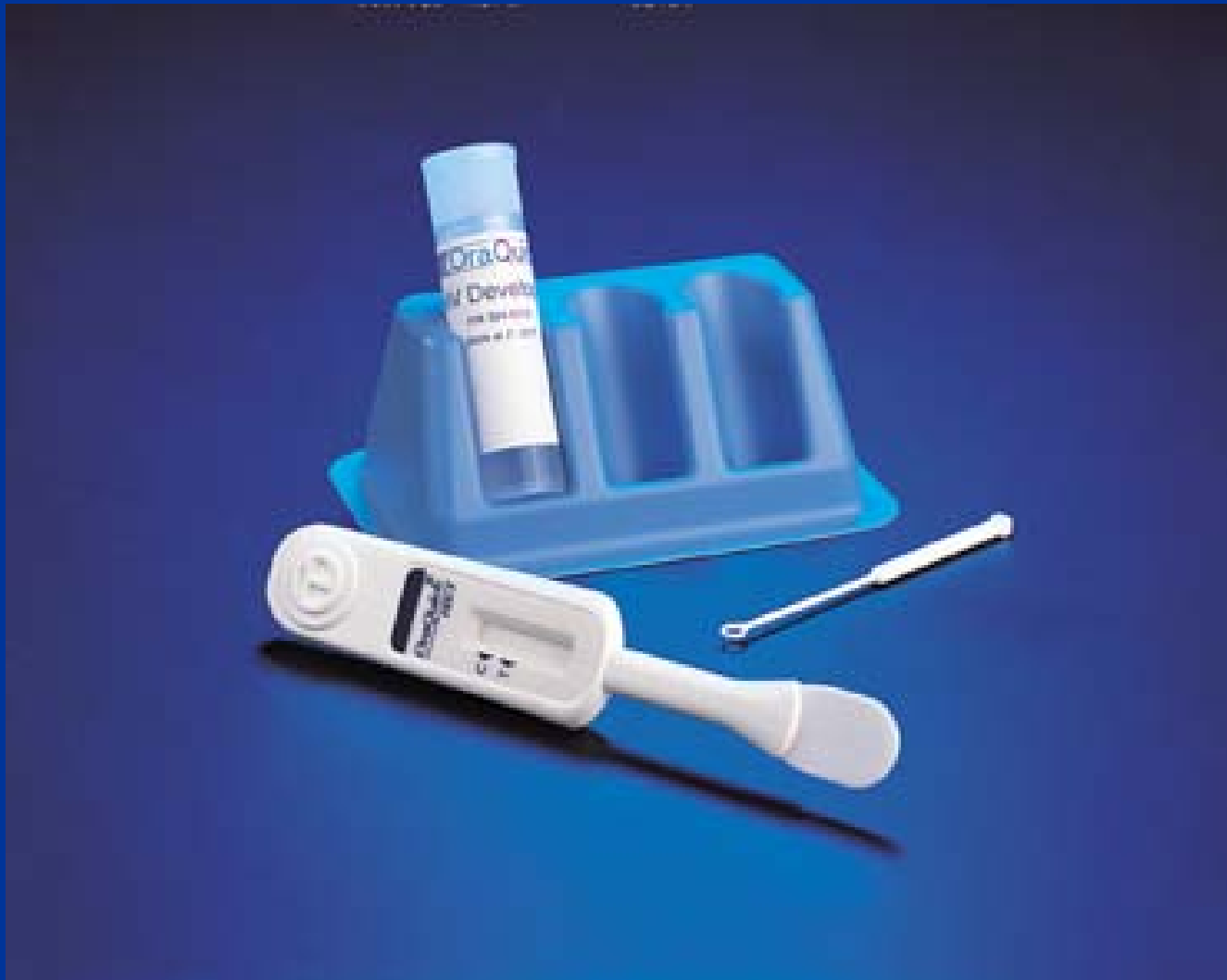
# Principle: Lateral flow devices



# Principle: Lateral flow devices



- Specimen flows along the membrane and **HIV antibodies** (*if present*) bind to the **HIV antigen** conjugated to the **colloidal gold** forming a visible red band
- The **anti-IgG/gold antibodies** at the control line bind to any unbound **colloidal gold** particles forming a visible red band.

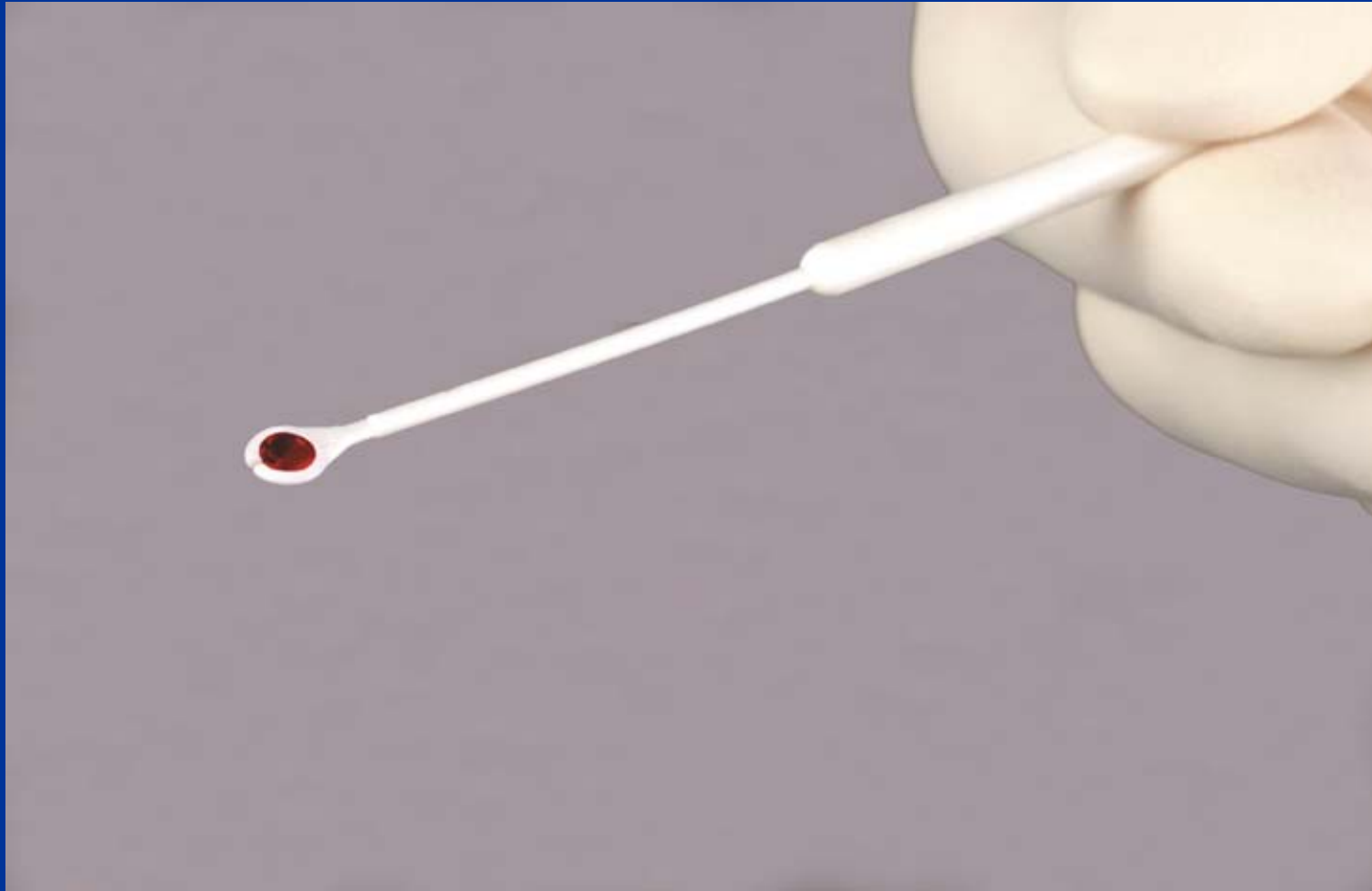


**OraQuick: Oral fluid, serum, whole blood**





**Obtain fingerstick blood specimen**



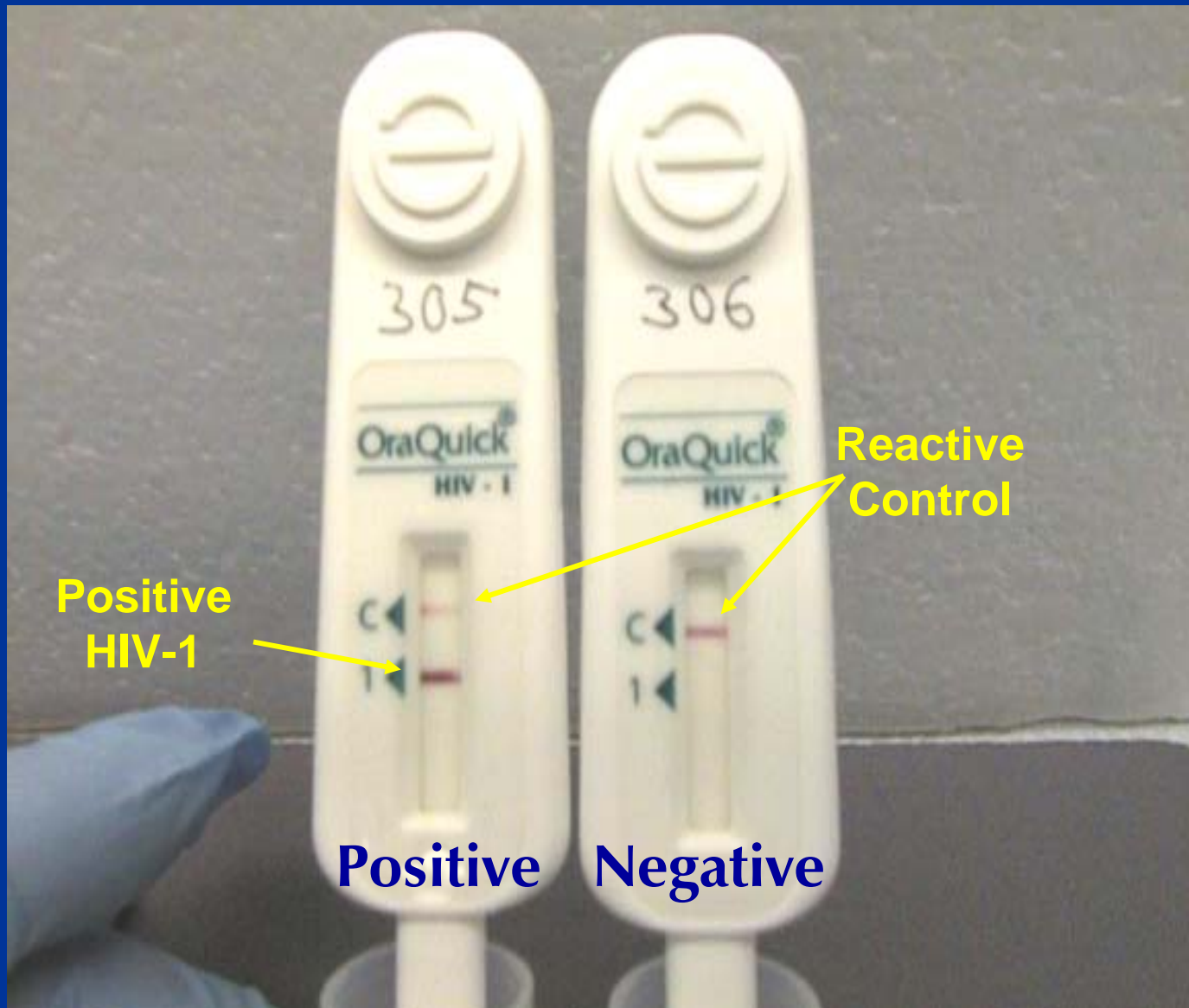
**Specimen loop with 5 microliters blood**



**Insert loop into vial and stir**



**Insert paddle into vial**



**Read results in 20 minutes**

# 2002 Consultation

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## ■ How...

- can we maximize the use of rapid HIV tests?
- can we maintain reliable, accurate test results?
- can we use rapid tests to reach people who have not been tested?
- do we accomplish all of these goals with a moderate complexity rapid HIV test?

# Acknowledgements

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